

Notice of Allowability

Application No.

10/519,723

Examiner

Patricia C. Mallari

Applicant(s)

BEN-OREN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 9/10/07.
2. ☒ The allowed claim(s) is/are 100-127.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

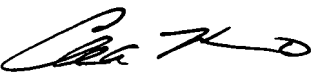
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Terminal Disclaimer

The terminal disclaimer filed on 9/10/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent Application No. 10/784117 has been reviewed and is accepted. The terminal disclaimer has been recorded.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

US Patent No. 6,548,043 to Wagner et al. discloses a method of determining gastric emptying comprising administering to a subject at least one or two meals comprising at least one constituent operative to cause retention of the meal(s) in the stomach of the subject, the meal having a predetermined volume. At least two measurements of a gastric emptying parameter of the meal(s) is performed after different volumes of the meal(s) have exited the stomach of the subject (see entire document, especially col. 2, lines 26-44; col. 7, lines 13-44; col. 8, line 35-col. 9, line 30 of Wagner). Wagner lacks evaluating the gastric accommodation of the subject from the measurements of the gastric emptying parameter as a function of the volume of the meal having exited the subject's stomach or according to the deviation between the at least one gastric emptying characteristic of said second meal and said at least one gastric emptying characteristic of said first meal.

US Patent No. 6,740,305 to Ajami teaches a method of determining gastric emptying in a subject, wherein at least one meal is administered to a subject, the meal

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having at least one constituent operative to cause retention of the meal in the subject's stomach and having a predetermined volume. At least one measurement of the slope of the gastric emptying curve or at least two measurements of a gastric emptying parameter of the meal is performed after different volumes of the meal have exited the stomach (see entire document, especially col. 10, line 65-col. 11, line 33 of Ajami).

Ajami lacks evaluating the gastric accommodation of the subject from either the slope of the gastric emptying curve or the gastric emptying parameter measurements, as claimed.

"Development of a test to measure gastric accommodation in humans" by Kuiken et al. discloses a method of a method for the evaluation of the gastric accommodation in a subject, wherein at least one meal is administered to a subject, the meal comprising at least one constituent operative to cause retention of the meal in the stomach of the subject and having a predetermined volume (see entire document, especially the abstract; pp.1218-1219 of Kuiken). Kuiken lacks performing any measurement of the slope of the gastric emptying curve or gastric emptying parameter and fails to evaluate the gastric accommodation of the subject from such measurements, as claimed.

Therefore, regarding claims 100-112, the primary reason for allowance is the inclusion of evaluating the gastric accommodation of the subject from said measurements of either one of the slope of the gastric emptying curve and a gastric emptying parameter as a function of the volume of the meal having exited the subject's stomach, in combination with all of the other limitations of the claims, which is not found in the prior art. Furthermore, with regard to claims 113-125, the primary reason for

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allowance is the inclusion of evaluating the gastric accommodation of the subject according to the deviation between the at least one gastric emptying characteristic of the second meal and the at least one gastric emptying characteristic of the first meal, in combination with all of the other limitations of the claims, which is not found in the prior art. As to claims 126 and 127, the primary reason for allowance is the inclusion of utilizing the gastric emptying rates to determine the gastric accommodation level of the subject, ascertaining the level of perceived dyspeptic symptoms of the subject at least upon administration of the first and second meals, and correlating the level of perceived dyspeptic symptoms of the subject with the volumes of the first and second meals to determine the level of visceral sensitivity, in combination with all of the other limitations of the claims, which is not found in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

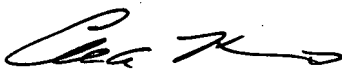
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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pcm


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